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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,507	10/04/2005	David Danvers Crossman	3003-1161	5480
<div>466 7590 08/31/2009</div> <div>YOUNG & THOMPSON</div> <div>209 Madison Street</div> <div>Suite 500</div> <div>ALEXANDRIA, VA 22314</div>				
EXAMINER				
PANI, JOHN				
ART UNIT		PAPER NUMBER		
3736				
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08/31/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,507

Applicant(s)

CROSSMAN ET AL.

Examiner

JOHN PANI

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S5108)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Specification

1. The amendment to the specification filed 5/19/2009 has been entered.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "or vice versa" of line 4 of claims 2 and 16 (i.e. an embodiment in which the locating member is a groove and the cooperating feature is a flange or rib) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5, 8-10, and 15-19 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Lines 9-10 of claim 1 and lines 15-16 of claim 15 recite "whereby the cap holds the lancet against movement relative to the housing". It is unclear exactly which previous limitation, structure, etc. "whereby" refers to, thereby rendering the claims indefinite.

Line 4 of claims 2 and 16 recite "or vice versa". It is unclear exactly how this limits the claims. For example, the claim could be interpreted to mean "the at least one locating member is a flange or rib and the at least one cooperating feature is a groove; or the at least one locating member is a groove and the at least one cooperating feature is a flange or rib" (as interpreted herein), or the claim could be interpreted to mean "the at least one locating member is a flange and the at least one cooperating feature is a rib", etc.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1, 2, 11, and 12 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 03/005907 to Koike et al. ("Koike").

Please note that US 2004/0243165 has been used herein as an English language translation for WO 03/005907, as US 2004/0243165 is a publication of the National Stage entry of PCT/JP02/07030. References to paragraph numbers below are made with respect to the US publication. It is noted that the drawing and reference numbers are identical for the two publications.

Koike teaches:

In reference to Claim 1

A blood sampling device comprising: a needle-carrying lancet (2) located within a housing (1) and having a cap (12") releasably attached to said lancet adjacent said needle (20), the cap extending to project from an attachment to said lancet through an opening at one end of the housing (see Fig. 16) and having at least one locating member (22" and grooves in 12" located to each side of 22") fitting into at least one cooperating feature (distal wall and distal opening of 1) of outer walls of the housing, whereby the cap holds the lancet against movement relative to the housing (see Fig. 16), the cap being twistable to release the at least one locating member from the at

least one cooperating feature such that the cap can be detached from the housing and from the lancet (see [0088]).

In reference to Claim 2

The blood sampling device of claim 1 (see above) wherein the at least one locating member is a flange or rib and the at least one cooperating is a groove, or vice versa (see Fig. 16).

In reference to Claim 11

A blood sampling device comprising: a housing (1) having an opening (space 22" resides in), a lancet body (2) carrying a needle (20), the lancet body being movably mounted within the housing and arranged so the needle momentarily projects through the opening of the housing upon actuating the blood sampling device (see Figs. 12A-12C), a cap (12") having a first end (23) releasably attached to the lancet body and covering a tip of the needle (Fig. 16), the cap extending through the opening of the housing to a second end that is releasably attached to the housing by at least one locating member (e.g. 22" and the groove in 12" surrounding 22") on the second end that fits into at least one cooperating feature (distal walls of 1 and distal opening in 1) on an outer wall of the housing, the cap being twistable to release the at least one locating member from the at least one cooperating feature so the cap can be removed from the housing and the lancet body (see [0088]), the cap, the housing and the lancet body being arranged to prevent forward movement of the needle relative to the housing prior to removal of cap and actuation of the blood sampling device (see Fig. 16).

In reference to Claim 12

The blood sampling device of claim 1 (see above) wherein the cap is twistable to remove the cap's attachment to the housing and the cap's attachment to the lancet (see [0088]).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4, 5, 8, 10, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,487,748 to Marshall et al. ("Marshall") in view of Koike.

In reference to Claims 4, 5, 8, 10, and 15

Marshall teaches a blood sampling device comprising: a housing (1, 2); a spring loaded (2) needle-carrying lancet (8) located within the housing; a cap (20) releasably attached to said lancet adjacent said needle (17); and a trigger releasable latch (23, 12, etc.) to hold the lancet within the housing such that an exposed needle cannot project through an opening at one end of the housing until the latch is released by the trigger (9) (see at least col. 3), the cap extending to project from an attachment to said lancet through the opening (4) at one end of the housing (Fig. 1), the cap being twistable to release the at least one locating member from the lancet (col. 3 lines 10-15), the lancet being spring-loaded to urge the lancet in a direction towards the opening in the housing, wherein said trigger releasable latch and said lancet have respective opposed latch

surfaces (12, 23) cooperable to retain said lancet in said housing until release of said latch, and said cap is adapted to hold the lancet in a position in which the lancet latch surface is spaced rearwardly of the latch surface of said trigger-releasable latch until said cap is detached from the lancet (see Fig. 1). Marshall further teaches that the device can be made in a pre-cocked version (col. 2 lines 40-50).

However, Marshall does not explicitly teach that the cap has at least one locating member fitting into at least one cooperating feature of outer walls of the housing, whereby the cap holds the lancet against movement relative to the housing, the cap being twistable to release the at least one locating member from the at least one cooperating feature such that the cap can be detached from the housing and from the lancet. Koike teaches a lancet device (see at least Fig. 16) in which the cap (12") has at least one locating member (22" and grooves in 12" surrounding 22") fitting into at least one cooperating feature (distal end of 1 in addition to distal hole in 1) of outer walls of the housing, whereby the cap holds the lancet against movement relative to the housing (see Fig. 16), the cap being twistable to release the at least one locating member from the at least one cooperating feature such that the cap can be detached from the housing and from the lancet (see [0088]). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device of Marshall by modifying the cap of the pre-cocked version so that it was attached to the outer walls of the housing as taught by Koike in order to provide a more secure shipping configuration as implicitly taught by Koike.

In reference to Claim 16

Marshall in view of Koike teaches the device of claim 15 (see above) and Koike teaches the at least one locating member is a flange or rib and the at least one cooperating feature is a groove, or vice versa (see Fig. 16).

9. Claims 3, 9, 13, 14, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koike or Marshall in view of Koike (as applicable) as applied to claims 1, 2, or 17 (as applicable) above, and further in view of US Pat. No. 3,165,220 to Haynes ("Haynes").

In reference to Claims 3, 13, 17, and 18

Koike teaches the device of claims 1 and 2 (see above). Marshall in view of Koike teaches the device of claim 15 (see above). However, neither Marshall nor Koike explicitly teach two flanges fitting into grooves in two opposed sides of outer walls of the housing or that the head of the cap can be rotated 90 degrees to release flanges from notches in two sides of the housing (see Fig. 5, a 90 degree rotation would release the flanges from the notches). Haynes teaches a tamper-proof container enclosure in which the cap includes two flanges (34) while the container includes grooves (18). The device includes frangible buttons/pins 28 which when broken, indicate that the original seal has been broken (see col. 1 line 60 – col. 2 line 60). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device of Koike or Marshall in view of Koike by including a tamper-proof enclosure using flanges, grooves, and pins as taught by Haynes, in the sealed cap taught by Koike, so the user could know whether the device was previously opened as taught by Haynes.

In reference to Claim 9

Marshall in view of Koike and Haynes teaches the device of claim 3 (see above), and Marshall further teaches the lancet is spring-loaded to urge the lancet in the direction towards the opening in the housing (via 7, see Fig. 1).

In reference to Claims 14 and 19

Marshall in view of Koike and Haynes teaches the device of claims 13 and 18 (see above) and Marshall further teaches the lancet can move forward until a ledge (23) on the lancet locates against a flange (12) on a trigger member.

Response to Arguments

10. Applicant's arguments, see pg. 8, "The Specification" and "Claim Objections", filed 6/2/2009, with respect to the specification and claim 4 have been fully considered and are persuasive. The objections of 6/2/2009 have been withdrawn.

11. Applicant's arguments regarding the Morita reference with respect to claims 1-5 and 8-11 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JP 8/27/09

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736

